PATENT

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Applicant(s):	Shaun Hanson	
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FIRST AMENDED APPEAL BRIEF UNDER 37 CFR § 41.37

This First Amended Appeal Brief is filed pursuant to the March 23, 2009 Notice of Appeal to the Board of Patent Appeals and Interferences and to the September 2, 2009 Notification of Non-Compliant Appeal Brief.

1. *Real Party in Interest*

The real party in interest in this appeal is Wright Medical Technology, Inc., the assignee of the above-referenced patent application.

2. *Related Appeals and Interferences*

There are no related appeals or interferences involving this application or its claimed subject matter.

3. *Status of Claims*

Claims 1-20 are pending. All claims stand rejected as unpatentable over a combination of prior art references as set forth in greater detail below. The prior art rejection of all pending claims is appealed herein.

4. *Status of Amendments*

The claims presented on appeal were last amended in a response filed on September 29, 2008. All amendments have been entered.

5. *Summary of Claimed Subject Matter*

The invention is an ulnar implant **10** for replacing the distal ulna. In the embodiment of independent **claim 1**, the implant **10** comprises an elongated stem **12** having first and second ends **16, 18**. (Specification, p. 9, lines 20-21; Figure 2). The first end **16** is sized and configured for insertion into the intramedullary canal of the distal ulna. (Specification, p. 9, lines 21-23). The second end **18** is configured for attachment to a head **14**. (Specification, p. 10, line 1; Figure 1). Suture holes **24, 26** are provided at or near the second end **18** for receiving sutures attaching the implant **10** to soft tissue. (Specification, p. 10, lines 6-7; Figures 1-2). The head **14** is separate from the stem **12** (See specification p. 9, lines 10-11; Figure 3). The head **14** has a triangulated portion when viewed from a distal end to substantially mimic normal anatomy. (Specification, p. 7, line 13; p. 10, lines 23-25, p. 1, lines 1-2; Figure 3). The head **14** is configured for mating with the sigmoid notch of the distal radius. *Id.* The head **14** is further configured for attachment to the second end **18** of the stem **12**. (Specification, p. 10, lines 25-27; p. 11, lines 4-12; Figure 1).

In the embodiment of independent **claim 12**, the ulna implant **10** comprises an elongated stem **12** having first and second ends **16, 18**. (Specification, p. 9, lines 20-21; Figure 2). The first

end **16** is sized and configured for insertion into the intramedullary canal of the distal ulna. (Specification, p. 9, lines 21-23). The second end **18** is configured for attachment to a head **14**. (Specification, p. 10, line 1; Figure 1). An extension **28** extends from the second end **18** of the stem **12**. (Specification, p. 10, lines 13-14; Figure 2). The extension **28** has proximal **34** and distal **30** portions and ends. (Specification, p. 10, lines 15-16, p. 11, lines 8-11; Figure 2). A suture hole **24** is provided in the distal portion **30** of the extension **28**. (Specification, p. 15, lines 15-17; Figure 2). A platform **22** is provided, the platform **22** being configured to prevent subsidence of the stem **12** into the ulnar canal. (Specification, p. 10, lines 1-4; Figures 1-2). The platform **22** is positioned at or near the proximal end **34** of the extension **28**. (Specification, p. 10, lines 1-2). Suture holes **26** are provided through the platform **22**. (Specification, p. 6, lines 9-11; p. 10, lines 17-18). The head **14** is separate from the stem **12** (See specification p. 9, lines 10-11; Figure 3). The head **14** has a triangulated portion when viewed from a distal end to mimic normal anatomy. (Specification, p. 7, line 13; p. 10, lines 23-25, p. 1, lines 1-2; Figure 3). The head **14** is configured for mating with the sigmoid notch of the distal radius. *Id.* The head **14** includes a bore **32** extending completely therethrough for receiving the extension **28** from the stem **12**, the extension of the stem **12** being configured such that the distal end **30** of the extension **12** extends completely through the bore **32**. (Specification, p. 10, lines 25-27; p. 11, lines 4-12; Figure 1).

Independent **Claim 16** is directed to a method for implanting a modular ulnar implant **10** in a patient. In the claimed method, the distal ulna of the patient is exposed and resected to expose the intramedullary canal of the ulna and the soft tissue that formerly surrounded the distal ulna. (Specification, p. 1, lines 22-30). An elongated stem **12** is provided, the elongated stem

having first and second ends **16, 18**. (Specification, p. 9, lines 20-21; Figure 2). The first end **16** is sized and configured for insertion into the intramedullary canal of the distal ulna, while the second end **18** is configured for attachment to a head **14**. (Specification, p. 9, lines 21-23; p. 10, line 1; Figure 1). Suture holes **24, 26** are provided at or near the second end **18** for receiving sutures attaching the implant to soft tissue. (Specification, p. 10, lines 6-7; Figures 1-2). A head **14** is provided. The head **14** has a triangulated portion when viewed from a distal end and is configured for mating with the sigmoid notch of the distal radius and for attachment to the second end **18** of the stem **12**. (Specification, p. 7, line 13, p. 10, lines 23-27; p. 11, lines 1-2 and 4-12; Figure 1; Figure 3). The stem **12** is inserted into the intramedullary canal of the distal ulna. (Specification, p. 12, lines 3-7). The stem **12** is sutured to soft tissue formerly surrounding the distal ulna. (Specification, p. 12, lines 18-20). The head **14** is attached to the stem **12**. (Specification, p. 12, lines 13-16; Figure 1).

6. ***Grounds of Rejection to be Reviewed on Appeal***

1. Whether claims 1-4 and 7-9 are properly rejected under 35 U.S.C. 103(a) as being obvious over Kapandji (FR 2,660,856A1).

2. Whether claim 10 is properly rejected under 35 U.S.C. 103(a) as being unpatentable over Kapandji (FR 2660856 A1) in view of Wack et al. (US 6,027,534).

3. Whether claims 1-9 and 11-20 are properly rejected under 35 U.S.C. 103(a) as being unpatentable over Cooney, III et al. (U.S. 6,302,915) in view of Stubstad (U.S. 3,745,590).

7. *Argument*

Ground 1: Whether claims 1-4 and 7-9 are properly rejected under 35 U.S.C. 103(a) as being obvious over Kapandji (FR 2,660,856A1)

Claims 1-4 and 7-9 are rejected under 35 U.S.C. 103(a) as being obvious over Kapandji (FR 2,660,856A1). Applicant traverses on grounds that Kapandji, even if modified as proposed by the Examiner, lacks several features of the claimed invention. Applicant further traverses on grounds that the proposed modification to Kapandji would render the reference inoperable for its intended purpose.

The Examiner takes the position that Kapandji discloses an implant 1 comprising a stem 20 and a head 4 (see Fig. 2), the implant having holes 26 passing through positions near both ends of the stem 20 and being capable of accepting a suture, and the head 4 including a 200 degree arc. The Examiner considers component 30 to be a portion of the platform or an extension, and further takes the position that component 30 includes holes 27 through which a suture could be passed. The Examiner concedes that Kapandji does not disclose a separate head.

In responding to previous 102(b) rejections over Kapandji, applicant has taken the position that Kapandji is being misinterpreted, but applicant has also amended claim 1 so as to directly address the deficiencies of Kapandji as a primary reference. Applicant initially amended claim 1 to specify that the head had a triangulated portion when viewed from a distal end, as shown in Figures 1 and 3. Applicant later amended claim 1 to specify that applicant's head 14 is a separate piece from the stem 12.

As can be seen in Figures 2, 3 and 4 of Kapandji, the cited reference teaches an implant that differs markedly in structure and function from that of the claimed invention. The Kapandji implant consists generally of a female part 2, a fixation means 30 for the female part 2, a male

part 3, and a fixation mean 7 for the male part. The female part 2 is implanted in a diaphyseal region of the ulna and is configured to ***articulate*** with the male part 3, which is implanted in a distal portion of the ulna. As shown in Kapandji Figures 3 and 4, the separate fixation means 7, 30 are configured to receive fixation screws 25, 44 in alignment with through bores in the stems 20, 40 of the respective female and male parts 2, 3. In applicant's view, significant modifications would be required in order to convert Kapandji into the claimed invention.

The Examiner interprets Kapandji component 4 as being a "head," but this component of Kapandji is in fact an open cavity 4 ("cavitié ouvert 4") that is formed in a well 10 ("un puits 10"). The Examiner takes the position that although the inner portion of the head of Kapandji has a cavity, this does not change the fact that the outer surface or extent thereof defines a head. However, it seems important that the open cavity 4 of the female part 2 *receives the round head 5 of the male part 3 in an articulating relationship*. When weight is given to these functional articulation features of Kapandji, it seems difficult to conclude that Kapandji component 4 is a "head" within the context of applicant's specification. If Kapandji's open cavity 4 were reconfigured as a head within the meaning of applicant's specification, it seems clear that the articulating relationship between Kapandji components 4 and 5 would be destroyed, rendering Kapandji inoperative for its intended purpose.

Further, the Examiner concedes that Kapanji does not have a separate head, but nonetheless takes the position that it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided the device of Kapandji with a head as a separate component from the stem, e.g., to facilitate manufacturing or to facilitate a minimally invasive procedure, since it has been held that constructing a formerly integral structure in

various elements involves only routine skill in the art, citing *Nerwin v. Erlichman*, 168 USPQ 177, 179. In view of the articulating structure found at element 4 of Kapandji, there would appear to be no reason to make the proposed modification. If element 4 were separated, it seems clear that the structurally integrity of the articulating components 4, 5, would be compromised. However, even if the foregoing modifications were made, Kapandji would still lack other features of the claimed invention.

With regard to the claimed triangulated portion of the head, the Examiner explains that the vertex and adjacent surfaces where the convex portion meets the planar face surrounding the cavity of Kapandji define what can be seen as a triangulated configuration, citing Kapandji Figure 2. With regard to applicant's June 27, 2008 claim amendment concerning the head being triangulated when viewed from a distal end, the Examiner takes the position that the triangulated configuration of Kapandji never ceases to exist regardless of whether or not it is prominent from a certain point of view. While it may well be possible to find a somewhat triangular shape in virtually any object that has a straight or planar portion, this differs from providing a "triangulated portion" as part of a specified configuration. It is respectfully submitted that no showing has been made that Kapanji teaches applicant's claimed separate "head having a triangulated portion when viewed from a distal end." The preferred embodiment shown in applicant's drawings has both a "triangulated portion" and an arc portion, and the use of "triangulated portion" when viewed from a distal end is therefore believed to distinguish over the prior art. Thus, applicant respectfully suggests that Kapandji's open cavity 4 cannot be interpreted as disclosing or functioning as a separate head having a triangulated portion within the meaning of applicant's claimed invention.

Applicant also does not agree that Kapandji teaches providing suture holes in the stem. While applicant agrees with the Examiner's observation that Kapandji's stem component 20 has through holes through which sutures are capable of being passed, applicant does not agree that Kapandji's screw holes are positioned in the manner claimed in claim 1. As can be seen clearly in Kapandji Figures 3-4, the Kapandji holes are lodged in the intramedullary canal of the bone, where they are not positioned at a second end for receiving sutures attaching the implant to soft tissue. Therefore, applicant does not understand how the Kapandji screw holes can be considered to be suture holes arranged as recited in the claim.

Thus, applicant respectfully submits that several limitation of the claimed subject matter of Claim 1-4 and 7-9 are neither taught nor suggested in the cited art. To establish *prima facie* obviousness of a claimed invention, all the claimed limitations must be taught or suggested by the prior art. *In re Royka*, 180 USPQ 580 (CCPA 1974). It has been noted repeatedly by the courts that "[a]ll words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 165 USPQ 494,496 (CCPA 1970). In *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 167 L.Ed.2d 705, 82 USPQ.2d 1385 (2007), the Supreme Court recently held that "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *Id.*, 127 S.Ct. at 1741. Accordingly, in the absence of a demonstration of elements being known in the prior art, *prima facie* obviousness is not established.

In *KSR*, the Supreme Court further cautioned that "[a] factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon ex post reasoning." Id., 127 S.Ct. at 1742, citing *Graham*, 383 U.S. at 36. In view of the missing

elements and arrangements, applicant respectfully submits that the rejection over Kapandji is based on hindsight reconstruction.

Ground 2. Whether claim 10 is properly rejected under 35 U.S.C. 103(a) as being unpatentable over Kapandji (FR 2660856 A1) in view of Wack et al. (US 6,027,534)

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kapandji (FR 2660856 A1) in view of Wack et al. (US 6,027,534).

The Examiner takes the position that Kapandji, if modified to include a separate head, discloses the claimed invention except for the bone ingrowth coating. The Examiner cited Wack et al. as disclosing a prosthetic implant 20 that has a bone ingrowth promoting coating provided on the device not only on the shaft thereof, but also on the backside of the main body, e.g. 15, thereof, in order to allow for bone ingrowth, which provides for more secure fixation (see, e.g., Fig. 1 and col. 3, line 65 - col. 4, line 18, esp. col. 4, lines 15-18). The Examiner takes the position that it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the implant of Kapandji with a bone ingrowth promoting coating, in view of Wack et al., in order to allow for bone ingrowth and provide more secure fixation of the implant.

While ingrowth surfaces are widely used in orthopedic implants, applicant submits that it is claiming the use of such a feature in conjunction with various other features and arrangements – such as for example a separate head having a triangulated portion – and that a *prima facie* showing has not been established as to the obviousness of the claimed combinations. For the reasons discussed above, applicant does not agree that the invention of claim 1, from which claim 10 depends, is disclosed in Kapandji. Thus, in applicant's view, the claimed use of an

ingrowth surface in relation to the claimed configuration of the complete implant structure is unique.

In addition to the uniqueness of the overall claimed implant structure, it is important to note that Claim 10 is directed to providing an ingrowth surface near the triangulated portion of the head in order to promote ingrowth with soft tissues. Based on the cited prior art, the claimed location of the ingrowth surface is unique with respect to the anatomy with which the ingrowth surface will interact upon implantation. Thus, it is respectfully suggested that while the use of ingrowth surfaces is well known to those of skill in the art, use of an ingrowth surface to promote ingrowth with soft tissues, at the particular recited location of the head, and in combination with the claimed implant structure, is unique.

For the foregoing reasons, applicant respectfully suggests that a *prima facie* showing of obviousness has not been established as to claim 10.

Ground 3. Whether claims 1-9 and 11-20 are properly rejected under 35 U.S.C. 103(a) as being unpatentable over Cooney, III et al. (U.S. 6,302,915) in view of Stubstad (U.S. 3,745,590)

Claims 1-9 and 11-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cooney, III et al. (U.S. 6,302,915) in view of Stubstad (U.S. 3,745,590). The Examiner takes the position that Cooney discloses the claimed invention except for the use of suture holes in portions of the device other than the head and except for the head having a through-bore. The Examiner notes that in Cooney, the head is a separate component from the stem. The Examiner takes the position that Stubstad discloses a similar device 10 and teaches attaching a ligature or suture 22 through both the head 11 and the stem 16 platform 19 structure in order to provide a continuity of strength through the prosthesis and resist dislocation of the joint to be corrected

while still providing unrestricted natural motion, citing Fig. 2; col. 1, lines 5-11; and col. 2, lines 44-47.

Applicant traverses on grounds that elements and arrangements of the claimed invention are not taught by the cited references, that there is no reason, motivation or suggestion to add the missing elements and arrangements, and that the missing elements and arrangements can be supplied only by relying on the teachings of applicant's disclosure to arrive at the claimed invention.

As previously noted, applicant does not agree with the Examiner's interpretation of Cooney and Stubstad. As far as applicant can determine, neither Cooney nor Stubstad teach various features of the claimed invention, including: a head having a triangulated portion when viewed from a distal end (independent claims 1, 12, 16); a head having a 200 degree arc in combination with a triangulated portion (dependent claims 9 and 13); a head having a through bore (independent claim 12; dependent claim 5); a head having a portion covered with an ingrowth coating at least near the triangulated portion (claims 10, 14); a stem having holes for receiving sutures (independent claims 12, 16; dependent claims 3, 4, 8); a stem having holes through a platform for receiving sutures (independent claim 12; dependent claims 3, 8); a stem having a suture hole at the end of an extension (claims 4, 8); and a method including suturing a stem having suture holes to various specified tissues (ulnar collateral capsule in dependent claim 18; triangular fibrocartilage in dependent claim 19; extensor carpi ulnaris subsheath in dependent claim 20).

Applicant submits that among the foregoing distinctions, sufficient originality is present to promote the progress of science and the useful arts by improving upon prior art references such as Cooney and Substad.

With regard to applicant's failure to appreciate how Cooney teaches a head having a triangulated portion when viewed from a distal end, the Examiner has noted that "In addition, in the same way that the Kapandji reference can be seen as showing a 'triangulated configuration,' so too can the Cooney reference, also at the vertex of the planar portion and the convex portion (as exemplified above in the diagram; cf. Cooney Fig. 3A)." While it may well be possible to find a somewhat triangular shape in virtually any object that has a straight or planar portion, this differs from providing a "triangulated portion" as part of a specified configuration. It is respectfully submitted that no showing has been made that Cooney teaches applicant's claimed "head having a triangulated portion when viewed from a distal end." Cooney specifically teaches a spherical structure for Cooney's head 12, as follows: "By cross-referencing FIGS. 1, 2 and 3A is can be seen that the head 12 is generally crown shaped and formed with a curved surface 18 for articulation with the sigmoid notch 20 of the distal radius 22." (Cooney, Col. 5, lines 4-8). As can be discerned from Cooney Figures 2 and 3A, Cooney would have a round configuration when viewed from a distal end, the only exception being in the area where Cooney provides a cutaway area and suture holes. However, Cooney's cutaway and suture holes occupy the region where applicant's triangulated portion would be located, and it therefore appears that Cooney teaches away from providing a triangulated portion in the same location. As far as applicant can determine, Clooney provides no reason for providing any configuration for the head 12 other than spherical or curved when viewed from the distal end.

The cited references fail to teach a head having a 200 degree arc in combination with a triangulated portion when viewed from a distal end, as recited in dependent claims 9 and 13.

The cited references fail to reach a head having a through bore, as recited in independent claim 12 and dependent claim 5. The Examiner maintains the position that it would have been obvious to have selected a bore depth in the head within a range resulting in a through bore, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art, such as for a given patient or surgical requirement, citing *In re Aller*, 105 USPQ 233. The Examiner concludes that providing a through bore is an obvious modification, and that doing so would hardly require a person of ordinary skill in the art to have to consult the applicant's disclosure to understand how or why to change the dimensions. However, there is no evidence in the record that providing an ulnar implant having a head having a through bore rather than a closed bore is simply a matter of using routine skill to discover an optimum or workable range. As such, a *prima facie* showing has not been made. Applicant fails to appreciate how a through bore can be considered to be an optimum or workable range, when in fact a through bore is a different structure that enables different functions, such as securing a separate head 14 via a suture passed through a through hole 24 in the distal end 30 of the extension 28. Applicant remains of the view that applicant's specification, rather than the cited references or ordinary skill in the art at the time of the invention, is in fact being consulted in order to modify the cited references to provide a through bore. With the benefit of applicant's disclosure, providing a head having a through bore may seem obvious in hindsight, but it is respectfully submitted that a *prima facie* case of obviousness

for applicant's teaching cannot be established merely by stating that providing a through bore is a matter of using ordinary skill to discover an optimum or workable range.

The prior art cited in combination against claim 14 does not teach a head having a portion covered with an ingrowth coating at least near the triangulated portion. While ingrowth surfaces are widely used in orthopedic implants, applicant submits that it is claiming the use of such a feature in conjunction with various other features and arrangements – such as for example a triangulated head – and that a *prima facie* showing has not been established as to the obviousness of the claimed combinations.

The cited prior art does not teach a stem having holes for receiving sutures, as recited in independent claims 12 and 16 and dependent claims 3, 4, 8. It is important to note that one of the objects of the invention is to improve over prior art ulnar implants such as Cooney by suturing the stem to the soft tissues. Applicant's application, at p. 11, lines 16-20, provided the following reasons why this feature provides functional advantages:

> Thus, using the modular ulnar implant of the invention, the implant is attached to the soft tissues 15 via the stem (or fixation component). By having the suture attachment means on the fixation component, a stem in a modular ulnar implant system, forces from the suture tissue attachment are transferred directly through the fixation component to the bone and not through the connection of the articulating component to the fixation component. As a result, there is no risk of separation of the head and stem due to biomechanical forces from the tissues attached by 20 suture to the implant.

Unlike applicant's specification, the cited references provide no such reason for suturing the stem (as opposed to the head) to the soft tissue. The Examiner takes the position that it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the implant of Cooney with holes in portions other than the head, such as the stem and platform, in view of Stubstad, in order to provide a continuity of strength through the prosthesis

and resist dislocation of the joint to be corrected while still providing unrestricted natural motion. However, the cited motivation or reason for the proposed modification to Cooney appears to be found in applicant's claims and at page 11, lines 16-20 of applicant's specification, rather than in the cited references. The Examiner has clarified that Stubstand is being cited for attaching the suture at the claimed locations. Although the Examiner maintains the position that Stubstad teaches attaching a ligature or suture 22 through both the Stubstad head 11 and stem 16 platform structure 19, applicant can locate no such teaching, including in the portions of Stubstad that are cited by the Examiner (Fig. 2; col. 1, lines 5-11; and col. 2, lines 44-47). Stubstand describes a unibody implant in which an affixed "ligamentous element" protrudes substantially along an edge of the articulating surface of the implant, as can be seen in all of Stubstad's figures. Stubstad does not discuss providing holes in the implant, but instead consistently describes the ligamentous element as being integral with or affixed to the implant. By disclosing an affixed ligamentous element adjacent the articular surface of a unibody implant, Stubstad appears to teach away from providing suture holes. Further, Studstand's teaching of a unibody implant (as opposed to a two part implant) having a ligamentous element adjacent the articular surface does not appear to add to the teaching of Cooney, since Cooney already teaches providing suture holes on the head adjacent the articular surface. For the reasons recited at p. 11, lines 16-20 of applicant's specification, applicant improves upon Cooney by, among other things, providing suture holes on the stem itself.

Even if Stubstand were somehow interpreted as furnishing a reason for providing suture holes on the Cooney stem, applicant submits that it remains a stretch to further conclude that the suture holes would be provided through the Cooney platform, in the manner recited in

independent claim 12 and dependent claims 3 and 8, and as shown in applicant's Figures 1-2. Further, even if Stubstand were somehow interpreted as furnishing a reason for providing suture holes through the Cooney platform, there is absolutely no reason in the cited references for providing a suture hole at the end of a stem extension, as recited in claims 4 and 8, as such an arrangement certainly provides a different arrangement and functionality than either Cooney or Stubstad.

The Examiner maintains that in the context of a surgical procedure, it would have been obvious to a person of ordinary skill in the art to have positioned the holes in the various claimed locations because this, too, has been held to be obvious, and doing so can accommodate, for example varying patient anatomy, conditions or other surgical requirements necessitating a modified installation. However, the fact that patient anatomies and surgical conditions differ does not establish a *prima facie* showing that those of skill at the time of the invention would have had a reason to locate suture holes in the manner taught by applicant's specification. Applicant is not merely relocating suture holes, but is claiming placement of the suture holes in the context of an implant that has a different structure and function than that of the cited references. Applicant remains of the view that applicant's specification, rather than the cited references, is being used to provide a reason for modifying the cited references to provide holes in the claimed locations. In *KSR*, the Supreme Court cautioned that "[a] factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning." Id., 127 S.Ct. at 1742, citing *Graham*, 383 U.S. at 36. Although the Examiner maintains that the motivations are derived from the references themselves *and* from the knowledge generally available to a person of ordinary skill in the art, it appears to

applicant that the motivation includes knowledge gleaned only from applicant's disclosure. It once again appears to applicant that its specification is being used as a blue print to engage in hindsight reconstruction of the claimed invention.

Finally, in method claims 16-20, applicant notes that the recited use of many of the above described features is not found in the prior art, and indeed the Examiner has made no attempt to locate such teachings in Cooney and Stubstad. Based on the record, applicant is aware of no basis for a *prima facie* showing that the cited art teaches a method including suturing a stem having suture holes to various specified tissues (ulnar collateral capsule in dependent claim 18; triangular fibrocartilage in dependent claim 19; extensor carpi ulnaris subsheath in dependent claim 20).

Thus, applicant respectfully submits that at least one limitation of the claimed subject matter of Claims 1-9 and 11-20 is neither taught nor suggested in the cited art. To establish *prima facie* obviousness of a claimed invention, all the claimed limitations must be taught or suggested by the prior art. *In re Royka*, 180 USPQ 580 (CCPA 1974). It has been noted repeatedly by the courts that "[a]ll words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 165 USPQ 494,496 (CCPA 1970). In *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 167 L.Ed.2d 705, 82 USPQ.2d 1385 (2007), the Supreme Court recently held that "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *Id.*, 127 S.Ct. at 1741. Accordingly, in the absence of a demonstration of elements being known in the prior art, *prima facie* obviousness is not established.

In *KSR*, the Supreme Court further recognized that there is no inconsistency between the idea underlying the longstanding teaching-suggestion-motivation test and the *Graham v. John Deere* analysis, provided that the teaching-suggestion-motivation test is not rigidly applied. *Id.*, 127 S.Ct. at 1741. *KSR* held that "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *Id.*, 127 S.Ct. at 1741. In the present case, where elements and arrangements of the claimed invention are not found in the references, applicant respectfully suggests that the teaching-suggestion-motivation test should be applied. While the Examiner has attempted to provide reasons for the proposed combinations of the cited references, it is respectfully suggested that these reasons are based on applicant's teachings, not motivations, suggestions or teachings found in the cited art. In the absence of a reason in the cited references that would have prompted a person of ordinary skill in the field to combine the elements in the manner of the claimed invention, much less to supply the missing elements, it is respectfully suggested that a *prima facie* showing of obviousness has not been established.

For the reasons set forth above, Applicants respectfully request that the Board overturn the rejections of record.

8. *Claims Appendix*

An appendix containing a copy of the claims involved in the appeal is attached below.

9. *Evidence Appendix*

None.

10. *Related Proceedings Appendix*

None.

CONCLUSION

In view of the foregoing arguments, Appellant respectfully submits that Claims 1-20 are patentable over the cited references. A decision from the Board of Patent Appeals and Interferences reversing the final rejection of the pending claims is therefore earnestly solicited.

Respectfully submitted,

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CLAIMS APPENDIX

1. (Previously presented) An ulnar implant for replacing the distal ulna after resection of the distal ulna, wherein the resection exposes soft tissue formerly in contact with the distal ulna, the implant comprising:

an elongated stem having first and second ends, the first end being sized and configured for insertion into the intramedullary canal of the distal ulna, the second end being configured for attachment to a head, wherein suture holes are provided at or near the second end for receiving sutures attaching the implant to the soft tissue;

a head, said head being a separate component from said stem, said head having a triangulated portion when viewed from a distal end to substantially mimic normal anatomy, the head being configured for mating with the sigmoid notch of the distal radius, and the head further being configured for attachment to the second end of the stem.

2. (Previously presented) The implant of claim 1, further including a platform at or near the second end of the stem, the platform being configured to prevent subsidence into the ulnar canal.

3. (Previously presented) The implant of claim 2, wherein the suture holes are provided through the platform.

4. (Previously presented) The implant of claim 1, further including an extension extending from the second end of the stem, the extension having proximal and distal ends, one of the suture holes being provided at a distal end of the extension.

5. (Previously presented) The implant of claim 4, wherein the head includes a bore extending completely therethrough for receiving the extension from the stem, the extension of

the stem being configured such that the distal end of the extension extends completely through the bore.

6. (Original) The implant of claim 5, wherein the extension and the bore are Morse tapers.

7. (Previously presented) The implant of claim 4, further including a platform configured to prevent subsidence into the ulnar canal, the platform being positioned at or near the proximal end of the extension.

8. (Original) The implant of claim 7, wherein the suture holes are provided through the platform and through the distal end of the extension.

9. (Original) The implant of claim 1, wherein the head includes a 200 degree arc for mating with the radial sigmoid notch.

10. (Previously presented) The implant of claim 1, wherein at least a portion of the head is covered with an ingrowth coating at least near the triangulated portion to promote ingrowth with the soft tissues.

11. (Original) The implant of claim 1, wherein the stem includes flutes at its first end to prevent rotation of the stem in the intramedullary canal of the distal ulna.

12. (Previously presented) An ulnar implant for replacing the distal ulna after resection of the distal ulna, wherein the resection exposes soft tissue formerly in contact with the distal ulna, the implant comprising:

an elongated stem having first and second ends, the first end being sized and configured for insertion into the intramedullary canal of the distal ulna, the second end being configured for attachment to a head;

an extension extending from the second end of the stem, the extension having proximal and distal portions and ends, a suture hole being provided in the distal portion of the extension;

a platform configured to prevent subsidence of the stem into the ulnar canal, the platform being positioned at or near the proximal end of the extension, wherein suture holes are provided through the platform; and

a head, said head being a separate component from said stem, the head having a triangulated portion when viewed from a distal end to mimic normal anatomy, the head being configured for mating with the sigmoid notch of the distal radius, and the head including a bore extending completely therethrough for receiving the extension from the stem, the extension of the stem being configured such that the distal end of the extension extends completely through the bore.

13. (Original) The implant of claim 12, wherein the head includes a 200 degree arc for mating with the radial sigmoid notch.

14. (Previously presented) The implant of claim 12, wherein at least a portion of the head is covered with an ingrowth coating at least near the triangulated portion to promote ingrowth with the soft tissues.

15. (Original) The implant of claim 12, wherein the stem includes flutes at its first end to prevent rotation of the stem in the intramedullary canal of the distal ulna.

16. (Previously presented) A method for implanting a modular ulnar implant in a patient, the method comprising the steps of:

exposing and resecting the distal ulna of the patient to expose the intramedullary canal of the ulna and the soft tissue that formerly surrounded the distal ulna;

providing an elongated stem having first and second ends, the first end being sized and configured for insertion into the intramedullary canal of the distal ulna, the second end being configured for attachment to a head, wherein suture holes are provided at or near the second end for receiving sutures attaching the implant to the soft tissue;

providing a head, the head having a triangulated portion when viewed from a distal end, the head configured for mating with the sigmoid notch of the distal radius, and the head further being configured for attachment to the second end of the stem;

inserting the stem into the intramedullary canal of the distal ulna;

suturing the stem to the soft tissue formerly surrounding the distal ulna; and

attaching the head to the stem.

17. (Original) The method of claim 16, wherein non-absorbable sutures are used to suture the stem to the soft tissue formerly surrounding the distal ulna.

18. (Original) The method of claim 16, wherein the stem is sutured to the ulnar collateral capsule.

19. (Original) The method of claim 16, wherein the stem is sutured to the triangular fibrocartilage.

20. (Original) The method of claim 16, wherein the stem is sutured to the extensor carpi ulnaris subsheath.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.